

FRISHAUF, HOLTZ, GOODMAN, LANGER & CHICK, P.C.
ATTORNEYS AT LAW

767 THIRD AVENUE, NEW YORK, N.Y. 10017-2023

STEPHEN H. FRISHAUF
LEONARD HOLTZ
HERBERT GOODMAN
WILLIAM R. WOODWARD (1914-1994)
THOMAS LANGER
MARSHALL J. CHICK
WALTER J. BAUM
RICHARD S. BARTH
DOUGLAS HOLTZ
ROBERT P. MICHAL

TELEPHONE: (212) 319-4900
TELEX: 236268
CABLE: EFEFPAT
FACSIMILES:
GROUP 3: (212) 319-5101
GROUP 4: (212) 644-4834

OF COUNSEL:

RICHARD M. GOLDBERG

June 6, 1997

Mr. Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Department of Health & Human Services
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, Maryland 20857

Re: Patent Term Extension for U.S. Patent 4,572,912
PRELAY™/REZULIN™ (troglitazone)
Your Docket No.: 97N-0145
Our Docket No.: 84566/HG

Dear Mr. Wilson:

This has reference to your letter dated May 21, 1997 to Mr. Stephen G. Kunin of the U.S. Patent and Trademark Office concerning the above-identified matter.

The second sentence of your May 21, 1997 letter referred only to New Drug Application (NDA) No. 20-719. However, it is noted that the human drug product identified in the patent term extension application, i.e., troglitazone, was assigned New Drug Application (NDA) No. 20-720 (for REZULIN™), as well as New Drug Application (NDA) No. 20-719 (for PRELAY™).

It would be appreciated if the FDA record in this matter refers to both NDA No. 20-719 and NDA No. 20-720.

Very truly yours,


Herbert Goodman
Attorney for Applicant

HG/ma

cc: Mr. Stephen G. Kunin
BOX PATENT EXTENSION